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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,881

02/24/2004

Mark L. Nelson

PAZ-222CNRCE

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/786,881	<b>Applicant(s)</b> NELSON ET AL.	
	<b>Examiner</b> Sabiha Qazi	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 26 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-26,38,40-44 and 46-282 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-26,38,40-44 and 46-282 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1612

**Non-Final Office Action**

Claims 1-3, 5-26, 38, 40-44 and 46-282 are pending. No claim is allowed at this time. Amendments are entered.

**Summary of this Office Action dated Tuesday May 27, 2008**

1. Continued Examination Under 37 CFR 1.114
2. Double Patenting Rejection
3. Rejection--35 USC § 112 (2)
4. Response to Remarks
5. Communication

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/26/2008 has been entered.

***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-3, 5-26, 38, 44, 46-282 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29, 75, 76, 79, 80-82, 89 and 90. of copending Application No. 11/490,867. Although the conflicting claims are not identical, they are not patentably distinct from each other because R9 in copending application

Art Unit: 1612

can be alkyl amino which has been claimed in the present application. Therefore, presently claimed invention is considered obvious to the claimed subject matter of the above co-pending application.

4. Examiner notes that in 11/490,867 there are two claims 79. One is cancelled.

Claims 1-3, 5-26, 38, 44, 46-282 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 11/330,700; 10/692,764; 10/737,361;; 10/877,928; 10/921,580; 10/943,571 10/996,119; 11/039,230; 11/348,608; 111490,867; 111810,336 and 111803,854. Although the conflicting claims are not identical, they are not patentably distinct from each other because each encompasses 9-aminomethyl tetracycline compounds as defined by the instant claims. Presently claimed invention is broad and covers the compounds of the cited co-pending application when R9 represents alkylamino group. However, the claimed compounds and/or the 9- aminomethyl groups recited by the instant claims are encompassed by the claims of the cited copending applications. See claim 1 in 10/921,580, 10/943,571, 11/039,230, See claim 26 of 10/737,361, and page 13, compound 1 and page 16, compound 7. See claim 1 and 54 in 10/692,764 and claim 47 in 10/996,119.

Amino alkyl group as defined in the specification represents large number of substituents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 16, 48-55, 62-82 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply:

Claim 16 is improperly dependent on claim 3.

Claim improperly dependent on claim 3. There no carbon link at 7-position. Claim 16 does not further limit claim 1. R-9 is aminoethyl wherein aminoalkyl has several definitions. Further claim 1 and 3 does not contain amino alkyl group.

**Claimed Subject Matter**

Claims are drawn to 9-aminoethyl substituted tetracyclines and their method of use.

**Response to Remarks**

- Applicants arguments are found persuasive therefore, rejection over (WO 01/87823) is withdrawn.
- Terminal Disclaimer on US Patent 7,326,696 has approved.
- Claims are amended and arguments are found persuasive therefore rejection under 102 (b) 48 under 35 U.S.C. 102(b) is withdrawn.

Art Unit: 1612

- Claims are amended therefore 112 (1) and double patenting rejection is withdrawn. In application 11/069197, R9 is hydrogen.

### **Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/  
Primary Examiner, Art Unit 1612